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<b>PRE-APPEAL BRIEF REQUEST FOR REVIEW</b>		Docket Number (Optional)  <b>JPD-4398-427</b>
Application Number  <b>10/533,928</b>	Filed  <b>July 29, 2005</b>	
First Named Inventor  <b>BERTHON-JONES</b>		
Art Unit  <b>3771</b>	Examiner  <b>Clinton Ostrup</b>	
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <input type="checkbox"/> Applicant/Inventor         </div> <div style="width: 45%; text-align: right;"> <u>/John P. Darling/</u> Signature         </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 45%;"> <input type="checkbox"/> Assignee of record of the entire interest. See 37 C.F.R. § 3.71. Statement under 37 C.F.R. § 3.73(b) is enclosed. (Form PTO/SB/96)         </div> <div style="width: 45%; text-align: right;"> <b>John P. Darling</b> _____ Typed or printed name         </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 45%;"> <input checked="" type="checkbox"/> Attorney or agent of record <u>44,482</u> (Reg. No.)         </div> <div style="width: 45%; text-align: right;"> <u>703-816-4887</u> Requester's telephone number         </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 45%;"> <input type="checkbox"/> Attorney or agent acting under 37CFR 1.34. Registration number if acting under 37 C.F.R. § 1.34 _____         </div> <div style="width: 45%; text-align: right;"> <u>March 24, 2009</u> Date         </div> </div> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.*</p> <p><input checked="" type="checkbox"/> *Total of <u>1</u> form/s are submitted.</p>		

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### **STATEMENT OF ARGUMENTS**

Applicants' representative invites the panel to review the arguments presented in the Response filed February 24, 2009.

Applicants also appreciate the courtesies extended by Supervisory Patent Examiner Yu and Examiner Ostrup to Applicants' representative at the personal interview conducted March 16, 2009. The points discussed during the interview are incorporated into the remarks below. See 37 C.F.R. §1.133b.

As discussed during the interview, each of independent claims 19 and 34 recites that the selected frame portion is engaged with the cushion so that the cushion is adjustable in accordance with a position of the selected frame portion relative to the main body of the frame. As noted by Applicants' representative during the interview, the brace 12 shown in Fig. 2 of Amarasinghe et al. (WO 02/45784 A1) does not engage with the cushion 16 in a manner that the cushion 16 is adjustable in accordance with a position of the brace 12 relative to the shell 13.

During the interview, Examiner Ostrup indicated that the term "engaged" in claims 19 and 34 was being interpreted with a dictionary definition which defines the term "engaged" as "bring together" or "to come together and interlock (as of machinery parts)" as defined in the Encyclopedia Britannica Online (Academic Edition) provided with the Interview Summary mailed March 23, 2009. Applicants' representative noted that during examination, the claims must be given their broadest reasonable interpretation consistent with the specification. As noted in M.P.E.P. §2111, the PTO applies to verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in Applicants' specification. As also noted in M.P.E.P. §2111, the broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach.

Applicants' representative argued that one of ordinary skill in the art would not interpret Amarasinghe et al.'s disclosure of the brace 12 being clipped to the mask shell 13 as the brace 12 being engaged with the cushion 16 so that the cushion 16 is adjustable in accordance with a position of the selected frame portion (i.e. brace 12) relative to the main body (i.e. shell 13).

Examiner Ostrup indicated that claims 19 and 34 were being interpreted as the selected frame portion, the cushion, and the main body being "engaged all together." As noted by Applicants' representative, however, this interpretation of claims 19 and 34 ignores the feature that the at least one selected frame portion's engagement with the cushion results in the cushion being adjustable in accordance with a position of the selected frame portion relative to the main

body. Examiner Ostrup indicated that the cushion 16 of Amarasinghe et al. is adjustable by adjustment of the headgear straps 14 or by the application of positive ventilation pressure to the mask assembly. As indicated in the March 23, 2009 Interview Summary, Examiner Ostrup has “taken the position that the frame portion (i.e. brace) 12 of Amarasinghe et al. is a detachable malleable wire and the cushion (16) is adjustable via the straps.”

It is respectfully submitted that this interpretation fails to present a *prima facie* case of anticipation. Claims 19 and 34 recite that the selected frame portion is engaged with the cushion so that the cushion is adjustable in accordance with the position of the selected frame portion relative to the main body. As noted in the Response filed February 24, 2009, and during the interview, the brace 12 of Amarasinghe et al. assumes a fixed predetermined position with respect to the mask shell 13. See, for example, page 6, lines 6-7 and 11-12, of Amarasinghe et al. Accordingly, even assuming the cushion 16 of Amarasinghe et al. were adjustable via the straps 14, such an interpretation would still fail to present a *prima facie* case of anticipation as neither claims 19 or 34 recite that the cushion is adjustable via a strap or straps. Claims 19 and 34 each recite that the cushion is adjustable in accordance with a position of the selected frame portion relative to the main body of the frame.

The standard of anticipation is identity of invention. In other words, the prior art must show the identical invention in as much detail as recited in the claim. See MPEP § 2131.

Examiner Ostrup also stated that as the brace 12 is removable from the mask shell 13, and the mask assembly may be removed from the patient and the brace 12 removed from the mask shell 13, such use of the mask assembly of Amarasinghe et al. would anticipate claims 19 and 34. It is again respectfully submitted that such an interpretation of Amarasinghe et al. ignores the feature of claims 19 and 34 that the engagement of the selected frame portion with the cushion results in the cushion being adjustable in accordance with a position of the at least one selected frame portion relative to the main body. Placing the mask brace 12 on the mask shell 13 of Amarasinghe et al. in a fixed, predetermined position that is a substantially constant position relative to the mask shell 13, and/or removing the mask brace 12 from the mask shell 13, does not result in any adjustment of the cushion 16. Accordingly, even under this interpretation of Amarasinghe et al., the prior art fails to disclose the identical inventions recited in claims 19 and 34.

Applicants’ representative also discussed the interpretation of Amarasinghe et al. that the brace 12 is engaged with the cushion 16 via the straps 14 and the shell 13, as argued on page 8, the last two lines, of the November 24, 2008 Office Action. It is respectfully noted that neither claim 19 nor claim 34 recites that the selected frame portion, the cushion, and the main body are

"all engaged together" or "engaged via a strap and/or a shell of the mask assembly." Claims 19 and 34 each recite that the selected frame portion is engaged with the cushion so that the cushion is adjustable in accordance with a position of the selected frame portion relative to the main body of the frame.

During the interview, Applicants' representative also discussed the interpretation of Fig. 2 of Amarasinghe et al. as allegedly showing that the brace head strap attachment points 15 of the brace 12 are engaged with the cushion 16 by "wrapping around" the cushion 16 when the straps 14 are fitted around a user's head. See, for example, page 3, lines 14-17, of the November 24, 2008 Office Action. There is simply no disclosure or suggestion whatsoever by Amarasinghe et al. that the brace head strap attachment points 15 "wrap around" the cushion 16, or engage with the cushion 16, as alleged in the Office Action. In fact, as Applicants' representative noted during the interview, the brace head strap attachment points 15 of the brace 12 extend outwardly from the mask shell 13 and do not engage the cushion 16 at all.

Examiner Ostrup alleged that because Amarasinghe et al. disclose that the brace 12 is malleable, that the brace head strap attachment points 15 would wrap around the cushion 16 upon tightening of the straps 14 and/or upon the application of positive ventilation pressure. As noted by Applicants' representative during the interview, the disclosure by Amarasinghe et al. that the brace 12 is malleable does not lead to the conclusion that the brace head strap attachment points 15 are bent during use of the mask so as to wrap around the cushion 16. There is simply nothing in the disclosure of Amarasinghe et al. that would support such an interpretation.

Anticipation is a question of fact. See, for example, In re Schreiber, 128 F.3d 1473, 1477 (Fed. Cir. 1997). The standard of review applied to findings of fact is the "substantial evidence" standard under the Administrative Procedure Act (APA). See In re Gartside, 203 F.3d 1305, 1315, 53 USPQ2d 1769, 1775 (Fed. Cir. 2000). Substantial evidence means "more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." Richardson v. Perales, 402 U.S. 389, 401 (1971).

As disclosed on page 8, lines 25-32, of Amarasinghe et al., the head gear may be disassembled from the mask while the headgear is engaged with the brace 12 without affecting strap length adjustment in order that the mask shell 13 and cushion 16 may be washed. The brace 12 and headgear assembly may be re-attached to the mask frame 13 without requiring the re-adjusting of the strap length. Once the brace 12 is located in the predetermined position relative to the mask frame 13, the head strap position relative to the mask frame 13 will resume the position it was in at the time the brace 12 was removed from the mask shell 13. This disclosure by Amarasinghe et al. makes it clear that although the brace 12 is malleable, the

adjustment of the straps 14 does not bend or “wrap around” any portion of the brace 12. As discussed during the interview, the application of typical treatment pressures in the range of 3-30 cm H<sub>2</sub>O, as disclosed on page 2, lines 2-3, of Amarasinghe et al., also will not result in the brace 12 being bent or “wrapped around” the cushion 16, as alleged by Examiner Ostrup.

It is respectfully submitted that Amarasinghe et al.’s disclosure of the brace 12 as malleable is not substantial evidence to support a conclusion that the brace head strap attachment points 15, or any other portion of the brace 12, “wrap around” the cushion 16. It is further respectfully submitted that the disclosure of Amarasinghe et al. on page 8, lines 25-32, discussed above, supports the opposite conclusion. The brace 12 may be removed from, and then re-attached to the mask shell 13, without requiring the re-adjustment of the strap 14. This is because the brace 12, including the brace head strap attachment points 15, assumes a fixed predetermined position relative to the mask shell 13 that is a substantially constant position relative to the mask shell 13, as disclosed on page 6, lines 11-12, of Amarasinghe et al.

During the interview, Examiner Ostrup also alleged that certain figures of Applicants’ specification supported the interpretation that the selected frame portion being engaged with a cushion means that the selected frame portion, the cushion, and the main body of the frame are “all engaged together.” In particular, Examiner Ostrup pointed to Fig. 53J of Applicants’ specification and the corresponding disclosure regarding this figure, generally found at paragraph [00204]. As noted by Applicants’ representative during the interview, there is nothing in the disclosure of Fig. 53J, or in the corresponding detailed description of this figure, that suggests that the recitation that the selected frame portion is engaged with the cushion means that the selected frame portion, the cushion, and the main body are “all engaged together.” During the interview, Applicant’s representative asked Examiner Ostrup to specify what portion of the description of Fig. 53J was being relied on to support the interpretation that “the selected frame portion being engaged with the cushion” would be understood by one of ordinary skill as the selected frame portion, the cushion and the main body being “engaged all together” or the selected frame portion being engaged with the cushion “via” the strap or the shell (as alleged on the last two lines of page 8 of the Office Action. Examiner Ostrup did not identify any portion of the description.

Furthermore, as Applicants’ representative noted during the interview, a rejection on the grounds of anticipation under 35 U.S.C. §102 requires that the prior art, not Applicants’ disclosure, disclose the invention as identically recited in the claims. Claims 19 and 34 recite that the selected frame portion is engaged with the cushion so that the cushion is adjustable in accordance with a position of the selected frame portion relative to the main body. Neither claim

19 or 34 recites that the selected frame portion, the cushion, and the main body are “all engaged together” or that the selected frame portion is engaged with the cushion “via” some other element.

There is also no requirement that every embodiment disclosed by Applicants “read on” the claimed invention. As discussed above, claim construction requires giving the claims their broadest reasonable interpretation consistent with the specification, not merely consistent with a single embodiment selected from multiple embodiments disclosed in the specification. As discussed during the interview, it is respectfully submitted that one of ordinary skill would not interpret the feature of claims 19 and 34 that the selected frame portion is engaged with the cushion so that the cushion is adjustable with a position of the selected frame portion relative to the main body as a recitation that the selected frame portion, the cushion, and the main body are “engaged all together.”

With respect to the conclusion of the March 23, 2009 Interview Summary that “the claim does not require the frame portion being directly in contact with the cushion,” Applicants agree. However, it is not Applicants’ position that Amarasinghe et al. fails to anticipate claims 19 and 34 because the brace 12 is not directly in contact with the cushion 16. It is Applicants’ position that Amarasinghe et al. fail to anticipate claims 19 and 34 because Amarasinghe et al. do not disclose the identical inventions recited in claims 19 and 34 because Amarasinghe et al. do not disclose that the brace 12 is engaged with the cushion 16 so that the cushion 16 is adjustable in accordance with a position of the brace 12 relative to the mask shell 13.